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REMARKS

This letter is responsive to a Final Office Action dated September 9, 2003. The applicant hereby notifies the Examiner that he has elected to respond pro se. A Revocation of Existing of Power of Attorney and New Power of Attorney is being filed concurrently.

In the Office Action, the Examiner finds that:

1) New material is rejected under 35 U.S.C. §132, including:

“to a tissue”;

“contacts a tissue surface”;

“at least two elongate elements”;

“wire”;

“against a tissue surface”;

“does not contact the tissue surface”;

“contacts the tissue surface”;

“periphery height along the axis of the nut that is equal to or less than the height of the band”;

“one or more prongs ... contact a tissue”;

“natural dissolution period such that during this period it substantially dissolved in vivo implantation and an inducible dissolution period”;

“against the tissue”; and

“against the tissue surface”.

2) Typographical error

3) Claims 65, 72, 75, 76, 77, 78, 80, 90, 91, 92, 93, 95, 99, 105, 106, 107, 108, 110, 112, 114 and 120-133 are rejected as being distinct inventions from the elected species.

4) Claim 74 is rejected as lacking antecedent basis for the limitation “the smaller diameter” and “the larger diameter”.

5) Claim 81 is rejected in that it contradicts claim 79 upon which it depends.

6) Claims 64, 66-71, 73, 74, 79, 81-89, 94, 96-98, 100-104 109, 111, 113, 115-119, and 134-137 are rejected under 35 U.S.C. §103(a) as being obvious over Seegmiller et al. in U.S. Patent No. 5,525,013.

1) Incorporation by Reference

The present application begins with the following paragraph:

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"The present application claims the priority of earlier filed international patent application serial no. PCT/IB00/00364 filed March 28, 2000; U.S. provisional application for patent serial no. 60/193,000 filed March 28, 2000; U.S. provisional application for patent serial no. 60/174,386 filed January 3, 2000; U.S. patent application serial no. [to be added] filed December 18, 2000, which is a divisional application of U.S. Patent Application Serial No. 08/601,177, filed February 14, 1996, now U.S. Patent No. 6,162,234, issued December 19, 2000, which is a continuation-in-part application of co-pending U.S. Patent application serial number 08/184,121, filed on January 21, 1994, which is a continuation-in-part application of U.S. Patent application serial number 08/034,269 filed March 23, 1993, the entire disclosures of which are hereby incorporated by reference."

MPEP §2163.07(b) states:

"Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application and should be treated as part of the text of the application as filed."

International patent application serial no. PCT/IB00/00364, incorporated into the instant application by reference, has been published as WO 01/49189.

A. Tissue Surface

The following quote, found on page 18, lines 10-18 of WO 01/49189, explains the final position of the suture nut as being against a tissue surface;

"Figs. 35-37 depict a suture nut as it is generally used to facilitate closure of an incision in a body tissue. ... The suture is pulled so that the suture nut *abuts* the tissue surface. ... Once the final stitch is made, the suture is tightened to close the incision and the second suture nut (64) is clamped onto the portion of the suture that is just exterior to the skin and part of the last stitch."

The above quote provides basis for the following claim language:

"to a tissue";

"contacts a tissue surface";

"against a tissue surface";

"against the tissue"; and

"against the tissue surface".

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B. "Periphery height"

Figs. 35-37 of WO 01/49189 depict the band around the nut in a manner that supports the claim language of:

"periphery height along the axis of the nut is equal to or *less* than the height of the band.";

C. Two Elongate Elements

Page 18, lines 19-23 of WO 01/49189 explain the use of two elongate elements:

"In an alternative embodiment, the suture nut includes a single enlarged bore or a pair of small bores which is adapted to receive two suture ends. This embodiment, a single suture nut can be used to grasp two difference portion of a suture simultaneously".

Figs. 38-40 of U.S. Patent No. 6,162,234, also included by reference, demonstrate just one of the many possible embodiments that incorporate two elongate elements.

D. Dissolvable / Inducible

Page 18, lines 26-27 of WO 01/49189 states:

"The suture nut is preferably constructed from one or more of the combinations of polymers used in dissolvable implants, some of which were noted above.

Page 16, lines 13-24 explain the nature of these polymers and their use:

"There are several known dissolvable materials used in orthopedic implant on the market today. The materials include for example G\PGA-TMC ... used in the Suretac™ soft tissue to bone tack by Acufex ... Each polymer combination can be varied to give the resultant implant specific properties, ... FIG. 28 depicts the use of a deterioration catalyst (57) such as an enzyme among other things ... that can induce the polymer to dissolve more rapidly and include, for example, hyaluronic acid."

This clearly provides basis for claim language of:

"natural dissolution period... and an inducible dissolution period".

E. Prongs / Does not Contact Tissue

Page 15, lines 19-21 of WO 01/49189 states:

"FIG. 24 depicts the split nut assembly being slid down the length of the threaded shaft and approaching the platform (54) of the pedestal (52)." As can be seen from Fig. 24, the

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pedestal comprises a series of prongs that space the split nut away from the skin surface.

The figures and explanation, therefor provide basis for the following claim language:

"does not contact the tissue surface"; and

"one or more prongs ... contact a tissue".

F. Wire

One standard form of suture comprises a "monofilament wire" in a variety of diameters. (See "monofilament suture" in Ethicon Suture (Johnson and Johnson) catalogue.) Hence "wire" is already covered by the language in the specification of suture.

2) Typographical error

Specification has been amended as above, changing the first R1 to R2, thereby correcting the typographical error.

3) Distinct Inventions From The Elected Species

Applicant respectfully disagrees with rejection of claims 65, 72, 75, 76, 77, 78, 80, 90, 91, 92, 93, 95, 99, 105, 106, 107, 108, 110, 112, 114 and 120-133.

MPEP §806.05(c)II states:

"If there is no evidence that combination AB_{sp} is patentable without the details of B_{sp}, restriction should not be restricted.

The above-noted claims are subspecies of the elected species as they contain all the limitations of independent claims 64, 79, 94 and 109.

4) Antecedent Language

Claim 73 has been amended, above, to provide antecedent basis for the limitation in claim 74 of "the smaller diameter" and "the larger diameter".

5) Claim 81 Contradicts Claim 79

Applicant respectfully disagrees with the Examiner rejection of claim 81 as claim 81 presents a different embodiment of claim 79. Claim 79 embodiment is a height that is less than the radial axis. Claim 81 embodiment is a height that is "equal to the height of the radial axis". As noted above, Figs. 35-37 of WO 01/49189 depict the band around the nut in a manner that supports the alternative embodiment.

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6) Obviousness over Seegmiller et al. – U.S. Patent No. 5,525,013.

Seegmiller et al. teach jaws that serve to compact or “crimp” together multiple strands of an industrial cable, as seen in Fig. 13. A separate nut is used to contact bearing plate 87, as stated in column 8, lines 22-25:

“cable 45 being held in place by jaws 63 ... with nut 23, of course being positioned directly against bearing plate 78.”

Another embodiment, shown in Figs. 20 and 21, show the jaws 63 around cable 80 while internal to cable sheath 107. As in all other embodiments, only nut 89 anchors cable 107 against plate 87.

In distinct contrast, the instant invention claims “An orthopedic fastening system ... for securing at least one elongate element to a tissue, *the system comprising two or more nut section that assemble to form a nut*”.

Additionally, it is not obvious to even contemplate the use of Seegmiller et al. for “securing ... to a tissue”, or anywhere near a tissue:

Seegmiller et al. teach a fastener that comprises metals that corrode during industrial use, but are substantially prevented from corroding through “the usage of epoxy-coated... cable” (Column 1, lines 15-16) that retard corrosion of the cable.

An epoxy-coated implant is not suitable for surgical use or in vivo implantation. Clearly, Seegmiller et al. teaches a different device than the instant invention that could not be even contemplated for our use.